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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,973	08/22/2001	Timothy P. Croughan	98A9-USC1 Croughan	8353

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PATENT DEPARTMENT
TAYLOR, PORTER, BROOKS & PHILLIPS, L.L.P
P.O. BOX 2471
BATON ROUGE, LA 70821-2471

EXAMINER	
KRUSE, DAVID H	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/934,973	CROUGHAN, TIMOTHY P.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-73 and 75-81* is/are pending in the application.

4a) Of the above claim(s) *63,65,67,69,71-73,76,78 and 80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *62,64,66,68,70,75,77,79 and 81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 12 January 2004 has been entered.

Election/Restrictions

2. The examiner has required restriction between product and process claims. Applicant's statement regarding rejoinder of the withdrawn process claim is noted (page 2 of the Remarks). Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR § 1.116; amendments submitted after allowance are governed by 37 CFR § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR § 1.104. Thus,

to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy. Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. Claims 62-73 and 75-81 are pending in the instant application.

4. Claims 63, 65, 67, 69, 71-73, 76, 78 and 80 remain withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4, filed 14 January 2003.

Information Disclosure Statement

5. The information disclosure statement filed 12 January 2004 has been considered, a signed copy is attached hereto.

Claim Rejections - 35 USC § 112

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 62, 64, 66, 68, 70, 75, 77, 79 and 81 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 25 July 2003. Applicant's arguments filed 12 January 2004 have been fully considered but they are not persuasive.

Applicant's arguments concerning the Preliminary Amendment filed 22 August 2001 are not found to be relevant to the instant rejection, which is not directed to the lack of written description based on new matter (page 3, 3rd paragraph of the Remarks).

Applicant argues that the present specification describes not just paper examples, not just a single example, not just a couple of examples, rather the specification describes in detail the actual reduction to practice of twenty-seven species of herbicide resistant rice in accordance with the present invention and that the actual reduction to practice of twenty-seven species, with ATCC deposits of twenty-two of those species, is more than ample to support generic claims (page 4, 1st and 2nd paragraphs of the Remarks). This argument is not found to be persuasive because Applicant describes the ATCC deposits as being produced by a mutagenesis method on

pages 10 and 11 of the specification, and that what describes the claimed genus is the general phenotype of imidazolinone and/or sulfonylurea herbicide resistance. The description of the exemplified rice plants in Tables 2, 3 and 4, of the specification, demonstrate that the exemplified rice plants have varying differences in their type of herbicide resistance profiles, and thus do not constitute a description of a genus of rice plants with a common structure. In *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), the issue was that a description of a method of obtaining a cDNA from a particular organism and the function of the encoded protein does not describe the cDNA. In the instant case, the description of a method of making imidazolinone and/or sulfonylurea herbicide tolerant rice plants using EMS mutagenesis does not describe the herbicide tolerant rice plants made as broadly claimed.

Applicant argues that the mutations are those that result in: a rice plant (1) that "is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase at levels of the herbicide that would normally inhibit the growth of a rice plant" and (2) that expresses "a functional acetohydroxyacid synthase that is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant" and thus whether a particular rice plant satisfies these limitations might, for example, be identified by a straight forward, two-part test: (1) determine whether the rice plant exhibits resistance to such a herbicide, under conditions that inhibit a control rice plant lacking herbicide resistance; and (2) determine whether the rice plant expresses an AHAS enzyme that is resistant at the enzyme level to normally

inhibitory levels of herbicide. Applicant also argues that examples of both types of tests are given in the specification on page 7, lines 13-30 (page 4, 4th paragraph of the Remarks). These arguments are not found to be persuasive for the reasons given supra, that a method of identifying a herbicide resistant rice plant does not adequately describe the claimed genus of herbicide-resistant rice plants.

Applicant argues that patent law imposes no requirement that an inventor must understand why an invention works, it is sufficient that the invention does in fact work. To the present day, the mechanism of herbicide resistance in ATCC 75295 is not understood, however, as the Office has previously recognized, for example, in issuing patent 5,545,822, which contains claims directed to rice line ATCC 75295 and its derivatives and progeny an inventor need not be able to explain why an invention works in order for the invention to be patentable. Applicant further argues that unlike some of the broader limitations appearing in other claims, the "ATCC 75295" limitation of Claim 81 is not directed to a generic description of a category of herbicide resistance but rather, that limitation requires specifically that "said plant is a derivative of the plant with ATCC accession number 75295, and said plant additionally has the herbicide resistance characteristics of the plant with ATCC accession number 75295", thus this limitation does not go beyond the written description (page 5, 2nd paragraph of the Response). These arguments are not found to be persuasive because this instant issue is not enablement ("understand why an invention works") but the issue of adequate written description of the claimed genus of herbicide-resistant rice plants. In addition, the issue of written description in US Patent 5,545,822 is moot because each application for

patent is examined on it's own merits. As to claim 81, because Applicant does not describe the specific mutation within ATCC 75295, one of skill in the art would not be able to recognize an infringing progeny herbicide-resistant rice plant from a rice plant made by another method.

In the instant claims, Applicant has claim any herbicide-resistant rice plant having resistant to any herbicide that normally inhibits acetohydroxyacid synthase (AHAS) at a level that normally inhibits the growth of a rice plant, and wherein said plant expresses an AHAS that is resistant to inhibition by at least one such herbicide (see claim 62). Because such a phenotype can arise from a myriad of mutations within multiple AHAS encoding genes within a rice plant and said herbicide-resistant rice plant could be produced by any of a multitude of methods, it remains unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

8. Claims 62, 64, 66, 68, 70, 75, 77, 79 and 81 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 25 July 2003. Applicant's arguments filed 12 January 2004 have been fully considered but they are not persuasive.

Applicant argues that all of their arguments put forth in the response filed 13 May 2003 had not been fully addressed (page 5 of the Remarks). In order to attempt to satisfy Applicant's misgivings, the Examiner has reexamined the response filed 13 May

2003 and can only find one issue that may have been overlooked. Applicant had argues that Applicant has now demonstrated that, in fact, several of the exemplified rice lines do have resistant AHAS enzymes and that none of the lines that have been tested has been found to lack a resistant enzyme and that enzyme-level assays have subsequently been conducted on several of the exemplified rice lines and the inventor's expectations have been confirmed (pages 13 and 14 of the response filed 13 May 2003). Applicant further states that international patent application WO 01/85970 discloses such evidence (page 14 of the response filed 13 May 2003). These argument are not found to be persuasive because Applicant states in the specification at the time of filing that "Because each of the herbicides tested inhibits the activity of acetohydroxyacid synthase, and because resistance to each of these herbicides has been demonstrated in the novel lines, it is expected that the novel herbicide resistance will show resistance to other herbicides that normally inhibit this enzyme." (page 28, last paragraph of the specification). In the instant case, Applicant has failed to enable the claims at the time of the invention within the full breadth of the claims. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors,

such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.".

Applicant's arguments that that the prior art rejections should be withdrawn is irrelevant to the instant rejection (page 6, 4th paragraph of the Remarks).

Applicant requests the Office to explain why the possible existence of other of herbicide resistance in rice, outside the scope of the claimed invention, would have a bearing on the question of enablement (page 6, 4th paragraph of the Remarks). The issue of other mechanisms for herbicide resistance to imidazolinone and/or sulfonylurea herbicides has been put forth because it is Applicant's burden to teach one of skill in the art at the time of the invention how to make and use the invention within the full scope of the claims. In the instant case, Applicant does not teach one of skill in the art how to make and use the invention as broadly claimed because it is unclear from the instant specification what the exact herbicide resistance mechanism in the exemplified rice plants is/are. The exemplified rice plants were produced by EMS mutagenesis, and thus would comprise a multitude of mutations, and thus Applicant did not teach the full scope of the mechanism of herbicide resistance at the time of the invention. In addition, the claims are directed to herbicide-resistant rice plant having any mutant AHAS gene encoding a herbicide resistant enzyme, which would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to practice within the full scope of the claims.

Applicant is reminded that the issue of enablement concerning the issued US Patent 5,952,553 is irrelevant to the instant rejection for the reason given supra (page 6,

5th paragraph of the Remarks). As to the issue of claim 81, the instant claim does not state that the herbicide resistance must come from ATCC 75295, just that it have its characteristics, hence it would require one of skill in the art to identify what characteristics produce herbicide resistance in ATCC 75295 and that of any progeny thereof and thus would constitute undue trial and error experimentation.

Claim Rejections - 35 USC § 102

9. Claims 62, 64, 66, 68 and 70 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Terakawa *et al* 1992 (Japan. J. Breed. 42:267-275). This rejection is repeated for the reason of record as set forth in the last Office action mailed 25 July 2003. Applicant's arguments filed 12 January 2004 have been fully considered but they are not persuasive.

Applicant argues that the disclosure of Terakawa *et al* is clearly distinguishable from the claimed inventions, that Applicant is attempting to obtain a sample of seed disclosed in the prior art reference and that if seed were no longer available that the prior art reference would be a nonenabling disclosure and cannot anticipate a claimed invention (page 7 of the Remarks). As stated in the previous Office action without evidence to the contrary, the rice plants disclosed by Terakawa *et al* inherently disclose the claimed invention. As to an enabling reference, Applicant's attention is directed to *In re Sivaramakrishnan*, 213 USPQ 441, 442 (CCPA 1982) which teaches that a prior reference does not necessarily have to reduce to practice a composition to describe such a composition, that a disclosure that teaches one of skill in the art how to make such a composition is sufficient.

Claim Rejections - 35 USC § 103

10. Claims 75, 77 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terakawa *et al* 1992 (Japan. J. Breed. 42:267-275) in view of Dietrich (U.S. Patent 5,767,361, filed 8 June 1992).

The teachings of Terakawa *et al* can be found in a previous Office action.

Terakawa *et al* do not specifically teach an imidazolinone resistant rice plant as claimed in claim 77.

Dietrich teaches that there were many different mutations know in the art at the time of Applicant's invention that produce sulfonylurea and imidazolinone resistance in plants (see column 2). The exemplified resistance in the corn cell line X112 is due to a substitution of serine-for-asparagine at amino acid position 621, which confers imidazolinone but not sulfonylurea herbicide resistance. Dietrich also teaches that it was know in the art at the time of Applicant's invention that plants comprise multiple loci encoding AHAS isozymes, and that mutations can occur in more than one loci to produce herbicide resistance (column 2, 2nd paragraph).

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to use the selection method of Terakawa *et al*, given the teachings of Dietrich, to select for imidazolinone and sulfonylurea resistant rice plants having mutations in a first and second AHAS. Terakawa *et al* motivates one of ordinary skill in the art to isolate other sulfonylurea resistant rice plants with altered ALS (syn. AHAS) (page 274, 2nd paragraph). Given the success of Terakawa *et al* in selecting sulfonylurea resistant rice plants with a mutant AHAS enzyme and the

teachings of Dietrich that other AHAS mutations were know in the art that produce imidazolinone and sulfonylurea herbicide resistances, one of ordinary skill in the art at the time of Applicant's invention would have had a reasonable expectation of success in making other herbicide-resistant rice plants.

Double Patenting

11. Claims 62, 64, 66, 68, 70, 75, 77, 79 and 81 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,773,704. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the issued Patent teach a herbicide-resistant rice plant that has the herbicide resistance characteristics of the plant deposited with ATCC accession number 97523. Because the issued claims to not limit the number of generations away from said deposited plant, the herbicide-resistant rice plant of the instant claims would be obvious, because one of ordinary skill in the art would not be able to distinguish the "derivative" plant of the patented herbicide-resistant rice plant from the "derivative" plant of the instant claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 25 July 2003. Applicant's arguments filed 12 January 2004 have been fully considered but they are not persuasive.

Applicant argues that under the correct legal standard, the proper comparison is between two claims and not a comparison between two embodiments and that obviousness-type double patenting questions often arise in the context of a broader genus claim verse a narrower species claim present in different patent(s) or

application(s) (page 9 of the Response). Applicant argues that "derivative" plants must retain the specified herbicide resistance characteristics, that the herbicide resistance characteristics are themselves typically distinguishable from one another and that different sources of herbicide resistance typically have different patterns of resistance to different levels of different herbicides (pages 9 and 10 of the Remarks). Applicant further argues that to support this ground of rejection, at a minimum the Office should identify at least one specific claim from the '704 patent and at least one specific claim from the present application, and then explain why a person of ordinary skill in the art would conclude that the latter would have been obvious in light of the former. It is respectfully submitted, however, that this is not the case (page 11 of the Remarks). In response to Applicant's arguments and request for clarification, the Examiner puts forth the following reasoning why the instant rejection is proper. At claim 1 of the '704 patent, Applicant has claimed a derivative of the plant having ATCC accession number 97523 having the herbicide resistance characteristics of said plant. At claim 62 of the instant application, Applicant claims a herbicide-resistant rice plant that is a derivative of a rice plant exposed to mutation-inducing conditions and expressing a functional acetohydroxyacid synthase that is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase. There is no teaching in either the instant specification or in the '704 patent what the herbicide resistance mutation is, and there is no limitation excluding reproducing the exact same mutation in another non-97523 rice plant that would be indistinguishable to one of ordinary skill in the art from a rice plant derived from the patented 97523-derived rice plant. Hence, it is the Examiner's opinion

that the instant claims are directed to a genus of herbicide-resistant rice plants that are rendered obvious in view of the species/subgenus covered by the '704 patent.

Applicant argues it should also be kept in mind that, as previously discussed, it is a nearly universal practice in the art that the developer or breeder of a new rice cultivar will disclose publicly the ancestry of the variety (except for a small number of proprietary hybrids) and as a practical matter one is very likely to know the perigee of any publicly released rice cultivar (page 10, last paragraph of the Remarks). This argument is not found to be persuasive for the reasons given in the previous Office action.

Applicant argues that nothing in claim 1 of the '704 patent teaches or suggests any herbicide resistant rice plant having a resistant AHAS enzyme other than the specific source of resistance from ATCC 97523, that there is no suggestion for how to make such a plant, and there would have been no reasonable expectation that such a plant could be successfully produced and that there would certainly have been no reasonable expectation that resistant rice AHAS enzymes could be produced having herbicide resistance characteristics different from those of the ATCC 97523 rice (page 13 of the Response). This argument has been addressed supra. As to the argument that there is not suggestion for how to make and use such a plant, at column 2, lines 37-55, the '704 patent teaches that examples of herbicide-resistant AHAS enzymes in plants other than rice were known in the art at the time of the invention, hence it would have been obvious to make others and one of ordinary skill in the art would have had a reasonable expectation of success, contrary to Applicant's assertion.

Conclusion

12. The rejection under 35 USC 103(a) of claims 75, 77 and 79 as being unpatentable over Croughan 1994 (Louisiana Agriculture 37(3): 25-26) in view of Terakawa *et al* 1992 (Japan. J. Breed. 42:267-275) is withdrawn in view of the new rejection under 35 USC 103(a).

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

David H. Kruse
AU 1638

David H. Kruse, Ph.D.
2 April 2004